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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/470,276	12/22/99	KOLODNER R	157/47483-C

HM12/0206

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EXAMINER	
FREDMAN,J	
ART UNIT	**PAPER NUMBER**
1655	11

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/470,276	Applicant(s) Kolodner et al
	Examiner Jeffrey Fredman	Group Art Unit 1655

☒ Responsive to communication(s) filed on *Jan 2, 2001*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-38* is/are pending in the application.

Of the above, claim(s) *1 and 13-38* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *2-12* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *5*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group II, claims 2-12 and SEQ ID Nos: 1, 3-6, 27-30 and 53, in Paper No. 9 is acknowledged. The traversal is on the ground(s) that each of the remaining sequences are human sequences. This is not found persuasive because this is not a reason to overcome a restriction requirement. Presumably the intention is to argue that the sequences lack patentable distinctness, however, the fact that sequences from two different vertebrate species are included is evidence that the sequences are distinct. With regard to burden, it would represent a significant burden to search each additional sequence.

The requirement is still deemed proper and is therefore made FINAL.

General

2. Claims 2-12 utilize the transitional term "having". Because this term lacks any particular meaning in the patent literature, the examiner will interpret "having" as being equivalent in scope to the open term "comprising".

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 5-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current claims are drawn to one of two broad genus, claims 5-9 being drawn to a genus comprising any "unique fragment" of SEQ ID NO: 1 and claim 10-11 being drawn to any primers which permit synthesis of a human mismatch repair gene, particularly hMSH5. This large genus is represented in the specification by only the named SEQ ID Nos. Thus, applicant has express possession of only one full length nucleic acid species and shows no fragments which are demonstrably unique and shows multiple primers in a genus which comprises hundreds of millions of different possibilities. The written description guidelines note regarding such genus/species situations that "Satisfactory disclosure of a ``representative number'' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.) Here, no common element or attributes of the sequences are disclosed, not even the presence of certain domains. No structural limitations or requirements which provide guidance on the identification of sequences which meet these functional limitations is provided.

Further, these claims encompass alternately spliced versions of the proteins, allelic variants including insertions and mutations, inactive precursor proteins which have a removable amino terminal end, and only specific nucleic acid sequences have been provided. No written description

of alleles, of upstream or downstream regions containing additional sequence, or of alternative splice variants has been provided in the specification.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only the nucleic acid and inherent amino acid sequence of the disclosed SEQ ID Nos are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception or written description of any nucleic acids acids which comprise "unique fragments" or which are modified by addition, insertion, deletion, substitution or inversion with the disclosed SEQ ID Nos.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 2-6, 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Sargent et al (EMBO J. (1989) 8(8):2305-2312).

Sargent teaches cosmid vectors which are transformed into E. Coli host cells (page 2311, column 2) which cosmid vectors comprise a double stranded nucleic acid (necessarily including sense and antisense strands) that includes the "G7" gene (page 2306, figure 1). Within figure 1, several cosmid vectors overlap the "G7" gene including F9N, F12M, FMC, FMEa nd EL3. The "G7" gene is inherently found to be the MSH5 gene claimed. With regard to points of similiarity, the "G7" gene is located on chromosome 6p21.3 as is the MSH5 gene, and the following is a partial sequence comparison of MSH5 and "G7", where MSH5 is the Qy sequence and "G7" is the database sequence.

```
  Query Match             89.5%;  Score 2596;  DB 68;  Length 3998;
  Best Local Similarity   97.1%;  Pred. No. 0;
  Matches 2675;  Conservative    0;  Mismatches   30;  Indels   51;  Gaps    1;

Qy     184 tcgccccacagggccttcagacccctttctttccaaaggagcctccaagctcatggcctcc 243
           |||  |  | ||||  |||   | |||          ||||||||||||||||||||||
Db       6 TCGGTCAGCGGGGCGTTCTCCCACCTGTAGCGACTCAGAGCCTCCAAGCTCATGGCCTCC 65

Qy     244 ttaggagcgaacccaaggaggacaccgcagggaccgagacctggggcggcctcctccggt 303
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      66 TTAGGAGCGAACCCAAGGAGGACACCGCAGGGACCGAGACCTGGGGCGGCCTCCTCCGGC 125

Qy     304 ttccccagcccggccccagtgccgggccccagggaggccgaggaggaggaagtcgaggag 363
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     126 TTCCCCAGCCCGGCCCCAGTGCCGGGCCCCAGGGAGGCCGAGGAGGAGGAAGTCGAGGAG 185

Qy     364 gaggaggagctggccgagatccatctgtgtgtgctgtggaattcaggatacttgggcatt 423
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     186 GAGGAGGAGCTGGCCGAGATCCATCTGTGTGTGCTGTGGAATTCAGGATACTTGGGCATT 245

Qy     424 gcctactatgatactagtgactccactatccacttcatgccagatgccccagaccacgag 483
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     246 GCCTACTATGATACTAGTGACTCCACTATCCACTTCATGCCAGATGCCCCAGACCACGAG 305

Qy     484 agcctcaagcttctccagagagttctggatgagatcaatccccagtctgttgttacgagt 543
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     306 AGCCTCAAGCTTCTCCAGAGAGTTCTGGATGAGATCAATCCCCAGTCTGTTGTTACGAGT 365

Qy     544 gccaaacaggatgagaatatgactcgatttctgggaaagcttgcctcccaggagcacaga 603
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     366 GCCAAACAGGATGAGAATATGACTCGATTTCTGGGAAAGCTTGCCTCCCAGGAGCACAGA 425
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Qy    604 gagcctaaaagacctgaaatcatatttttgccaagtgtggattttggtctggagataagc 663
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    426 GAGCCTAAAAGACCTGAAATCATATTTTTGCCAAGTGTGGATTTTGGTCTGGAGATAAGC 485

Qy    664 aaacaacgcctcctttctggaaactactccttcatcccagacgccatgactgccactgag 723
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    486 AAACAACGCCTCCTTTCTGGAAACTACTCCTTCATCCCAGACGCCATGACTGCCACTGAG 545

Qy    724 aaaatcctcttcctctcttccattattccctttgactgcctcctcaca------------ 771
          ||||||||||||||||||||||||||||||||||||||||||||||||
Db    546 AAAATCCTCTTCCTCTCTTCCATTATTCCCTTTGACTGCCTCCTCACACCCCCAGGAGAT 605

Qy    772 ----------------------------------------gttcgagcacttggagggctg 792
                                                     ||||||||||||||||||||
Db    606 TTAAGATTTACCCCGATTCCACTGCTGATCCCCTCCCAGGTTCGAGCACTTGGAGGGCTG 665

Qy    793 ctgaagttcctgggtcgaagaagaatcggggttgaactggaagactataatgtcagcgtc 852
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    666 CTGAAGTTCCTGGGTCGAAGAAGAATCGGGGTTGAACTGGAAGACTATAATGTCAGCGTC 725

Qy    853 cccatcctgggctttaagaaatttatgttgactcatctggtgaacatagatcaagacact 912
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    726 CCCATCCTGGGCTTTAAGAAATTTATGTTGACTCATCTGGTGAACATAGATCAAGACACT 785

Qy    913 tacagtgttctacagatttttaagagtgagtctcacccctcagtgtacaaagtggccagt 972
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    786 TACAGTGTTCTACAGATTTTTAAGAGTGAGTCTCACCCCTCAGTGTACAAAGTGGCCAGT 845

Qy    973 ggactgaaggaggggctcagcctctttggaatcctcaacagatgccactgtaagtgggga 1032
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    846 GGACTGAAGGAGGGGCTCAGCCTCTTTGGAATCCTCAACAGATGCCACTGTAAGTGGGGA 905

Qy   1033 gagaagctgctcaggctatggttcacacgtccgactcatgacctgggggagctcagttct 1092
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    906 GAGAAGCTGCTCAGGCTATGGTTCACACGTCCGACTCATGACCTGGGGGAGCTCAGTTCT 965

Qy   1093 cgtctggacgtcattcagttttttctgctgccccagaatctggacatggctcagatgctg 1152
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    966 CGTCTGGACGTCATTCAGTTTTTTCTGCTGCCCCAGAATCTGGACATGGCTCAGATGCTG 1025

Qy   1153 catcggctcctgggtcacatcaagaacgtgccttgattctgaaacgcatgaagttgtcc 1212
          ||||||||||||||||||||||||||||||||| ||||||||||||||||||||||||||||
Db   1026 CATCGGCTCCTGGGTCACATCAAGAACGTGCCTCTGATTCTGAAACGCATGAAGTTGTCC 1085

Qy   1213 cacaccaaggtcagcgactggcaggttctctacaagactgtgtacagtgccctgggcctg 1272
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db   1086 CACACCAAGGTCAGCGACTGGCAGGTTCTCTACAAGACTGTGTACAGTGCCCTGGGCCTG 1145

Qy   1273 agggatgcctgccgctccctgccgcagtccatccagctctttcgggacattgcccaagag 1332
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db   1146 AGGGATGCCTGCCGCTCCCTGCCGCAGTCCATCCAGCTCTTTCGGGACATTGCCCAAGAG 1205

Qy   1333 ttctctgatgacctgcaccatatcgccagcctcattgggaaagtagtggactttgagggc 1392
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db   1206 TTCTCTGATGACCTGCACCATATCGCCAGCCTCATTGGGAAAGTAGTGGACTTTGAGGGC 1265

Qy   1393 agccttgctgaaaatcgcttcacagtcctccccaacatagatcctgaaattgatgagaaa 1452
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db   1266 AGCCTTGCTGAAAATCGCTTCACAGTCCTCCCCAACATAGATCCTGAAATTGATGAGAAA 1325

Qy   1453 aagcgaagactgatgggacttcccagtttccttactgaggttgcccgcaaggagctggag 1512
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db   1326 AAGCGAAGACTGATGGGACTTCCCAGTTTCCTTACTGAGGTTGCCCGCAAGGAGCTGGAG 1385
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Qy   1513 aatctggactcccgtattccttcatgcagtgtcatctacatccctctgattggcttcctt 1572
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db   1386 AATCTGGACTCCCGTATTCCTTCATGCAGTGTCATCTACATCCCTCTGATTGGCTTCCTT 1445

Qy   1573 ctttctattccccgcctgccttccatggtagaggccagtgactttgagattaatggactg 1632
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db   1446 CTTTCTATTCCCCGCCTGCCTTCCATGGTAGAGGCCAGTGACTTTGAGATTAATGGACTG 1505

Qy   1633 gacttcatgtttctctcagaggagaagctgcactatcgtagtgcccgaaccaaggagctg 1692
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db   1506 GACTTCATGTTTCTCTCAGAGGAGAAGCTGCACTATCGTAGTGCCCGAACCAAGGAGCTG 1565

Qy   1693 gatgcattgctgggggacctgcactgcgagatccgggaccaggagacgctgctgatgtac 1752
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db   1566 GATGCATTGCTGGGGGACCTGCACTGCGAGATCCGGGACCAGGAGACGCTGCTGATGTAC 1625

Qy   1753 cagctacagtgccaggtgctggcacgagcagctgtcttaacccgagtattggaccttgcc 1812
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db   1626 CAGCTACAGTGCCAGGTGCTGGCACGAGCAGCTGTCTTAACCCGAGTATTGGACCTTGCC 1685

Qy   1813 tcccgcctggacgtcctgctggctcttgccagtgctgcccgggactatggctactcaagg 1872
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db   1686 TCCCGCCTGGACGTCCTGCTGGCTCTTGCCAGTGCTGCCCGGGACTATGGCTACTCAAGG 1745

Qy   1873 ccgcgttactccccacaagtccttggggtacgaatccagaatggcagacatcctctgatg 1932
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db   1746 CCGCGTTACTCCCCACAAGTCCTTGGGGTACGAATCCAGAATGGCAGACATCCTCTGATG 1805

Qy   1933 gaactctgtgcccgaacctttgtgcccaactccacagaatgtggtggggacaaagggagg 1992
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db   1806 GAACTCTGTGCCCGAACCTTTGTGCCCAACTCCACAGAATGTGGTGGGGACAAAGGGAGG 1865

Qy   1993 gtcaaagtcatcactggacccaactcatcagggaagagcatatacctcaaacaggtaggc 2052
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db   1866 GTCAAAGTCATCACTGGACCCAACTCATCAGGGAAGAGCATATACCTCAAACAGGTAGGC 1925

Qy   2053 ttgatcacattcatggccctggtaggcagctttgtgccagcagaggaggccgaaattggg 2112
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db   1926 TTGATCACATTCATGGCCCTGGTAGGCAGCTTTGTGCCAGCAGAGGAGGCCGAAATTGGG 1985

Qy   2113 gcagtagacgccatcttcacacgaattcatagctgcgaatccatctcccttggcctctcc 2172
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db   1986 GCAGTAGACGCCATCTTCACACGAATTCATAGCTGCGAATCCATCTCCCTTGGCCTCTCC 2045

Qy   2173 accttcatgatcgacctcaaccaggtggcgaaagcagtgaacaatgccactgcacagtcg 2232
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db   2046 ACCTTCATGATCGACCTCAACCAGGTGGCGAAAGCAGTGAACAATGCCACTGCACAGTCG 2105

Qy   2233 ctggtccttattgatgaatttggaaagggaaccaacacggtggatgggctcgcgcttctg 2292
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db   2106 CTGGTCCTTATTGATGAATTTGGAAAGGGAACCAACACGGTGGATGGGCTCGCGCTTCTG 2165

Qy   2293 gccgctgtgctccgacactggctggcacgtggacccacatgccccacatctttgtggcc 2352
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db   2166 GCCGCTGTGCTCCGACACTGGCTGGCACGTGGACCCACATGCCCCACAGTCTTTGTGGCC 2225

Qy   2353 accaactttctgagccttgttcagctacaactgctgccacaagggcccctggtgcagtat 2412
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db   2226 ACCAACTTTCTGAGCCTTGTTCAGCTACAACTGCTGCCACAAGGGCCCCTGGTGCAGTAT 2285

Qy   2413 ttgaccatggagacctgtgaggatggcaacgatcttgtcttcttctatcaggtttgcgaa 2472
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db   2286 TTGACCATGGAGACCTGTGAGGATGGCAACGATCTTGTCTTCTTCTATCAGGTTTGCGAA 2345

Qy   2473 ggtgttgcgaaggccagccatgcctcccacacagctgcccaggctgggcttcctgacaag 2532
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          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    2346 GGTGTTGCGAAGGCCAGCCATGCCTCCCACACAGCTGCCCAGGCTGGGCTTCCTGACAAG 2405

Qy    2533 cttgtggctcgtggcaaggaggtctcagatttgatccgcagtggaaaacccatcaagcct 2592
          ||||||||||||||||||||||||||||| ||||||||||||||||||||||||||||||||
Db    2406 CTTGTGGCTCGTGGCAAGGAGGTCTCAGACTTGATCCGCAGTGGAAAACCCATCAAGCCT 2465

Qy    2593 gtcaaggatttgctaaagaagaaccaaatggaaaattgccagacattagtggataagttt 2652
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    2466 GTCAAGGATTTGCTAAAGAAGAACCAAATGGAAAATTGCCAGACATTAGTGGATAAGTTT 2525

Qy    2653 atgaaactggatttggaagatcctaacctggacttgaacgttttcatgagccaggaagtg 2712
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    2526 ATGAAACTGGATTTGGAAGATCCTAACCTGGACTTGAACGTTTTCATGAGCCAGGAAGTG 2585

Qy    2713 ctgcctgctgccaccagcatcctctgagagtccttccagtgtcctccccagcctcctgag 2772
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    2586 CTGCCTGCTGCCACCAGCATCCTCTGAGAGTCCTTCCAGTGTCCTCCCCAGCCTCCTGAG 2645

Qy    2773 actccggtgggctgccatgccctctttgtttccttatctccctcagacgcagagtttttta 2832
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    2646 ACTCCGGTGGGCTGCCATGCCCTCTTTGTTTCCTTATCTCCCTCAGACGCAGAGTTTTTA 2705

Qy    2833 gtttctctagaaattttgtttcatattaggaataaagtttatttttgaagaaaaaaa 2888
          |||||||||||||||||||||||||||||||||||||||||||||||||||||| | |
Db    2706 GTTTCTCTAGAAATTTTGTTTCATATTAGGAATAAAGTTTATTTTGAAGAAAGATA 2761
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Therefore, it clearly appears that the Sargent cosmid vectors anticipate the current claims as inherently comprising the MSH5 gene sequence.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albertella (Genomics (1996) 36:240-251) in view of Stratagene Catalog (1988) p. 39.

Albertella teaches a number of primers which function to amplify the "G7" gene region (page 241, column 2, subheading "reverse-transcription-PCR" to page 242, column 1). As discussed above, "G7" is inherently found to be the MSH5 gene.

Albertella does not teach placement of these reagents into a kit format, nor the specific SEQ ID Nos: 3-50.

Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the primers of Albertella into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantitites of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer

solutions from the basic reagents. Stratagene provides only the quantitites you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control" (page 39, column 1).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to identify functionally equivalent primers and probes selected from the sequences disclosed by Albertella for detection of the "G7" gene.

In the recent court decision *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the court determined that the existence of a general method of identifying a specific DNA does not make the the specific DNA obvious. Regarding structural or functional homologs, however, the court stated

> "Normally, a *prima facie* case of obviousness is based upon structural similiarity, i.e., an established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties (see page 9, paragraph 4 of attached ref)."

Since the claimed primers simply represent structural homologs, which are suggested by the prior art as useful for primers and probes, and concerning which a biochemist of ordinary skill would

attempt to obtain alternate compounds with improved properties, the claimed primers and probes are *prima facie* obvious over the cited references in the absence of secondary considerations.

9. Claims 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sargent et al (EMBO J. (1989) 8(8):2305-2312) in view of Beach et al (U.S. Patent 6,025,192).

Sargent teaches cosmid vectors which are transformed into E. Coli host cells (page 2311, column 2) which cosmid vectors comprise a double stranded nucleic acid (necessarily including sense and antisense strands) that includes the "G7" gene (page 2306, figure 1). Within figure 1, several cosmid vectors overlap the "G7" gene including F9N, F12M, FMC, FMEa nd EL3. The "G7" gene is inherently found to be the MSH5 gene claimed. With regard to points of similiarity, the "G7" gene is located on chromosome 6p21.3 as is the MSH5 gene, and above is listed the partial sequence comparison of MSH5 and "G7", where MSH5 is the Qy sequence and "G7" is the database sequence.

Sargent does not teach placement of the G7 gene into a retroviral vector.

Beach teaches placement of genes into retroviral vectors for the elucidation of mammalian gene function (abstract).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to put the unknown G7 gene of Sargent into the retroviral vector of Beach since Beach states "The present invention relates to methods and compositions for the elucidation of mammalian gene function (abstract)". An ordinary practitioner would have been motivated to use the retroviral vector of Beach to identify the function of G7.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeff Fredman, Ph.D. whose telephone number is (703) 308-6568.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Jeffrey Fredman
Patent Examiner
Art Unit 1655

February 6, 2001